

Application No.: 10/524,956
Response dated September 29, 2008
Reply to Office action of April 2, 2008

REMARKS/ARGUMENTS

Applicants thank the Examiner for the thorough review of the application.

Claims 1-5 and 8 are amended. Claims 6, 9-11 and 14 are cancelled. Claims 1-5 and 8 are pending in the application.

The amendments are made without prejudice or disclaimer. Applicants expressly reserve the right to pursue the cancelled subject-matter in divisional or continuation applications.

No new matter has been added by way of this amendment, the entry of which is respectfully requested. Please note the new Attorney Docket No. (01-2113).

Non-elected claims

Claims 6, 9-11 and 14 are cancelled as being non-elected. Applicants reserve the right to pursue the subject-matter of claims 6, 9-11 and 14 in divisional applications.

Specification

A new Title of the Invention is provided.

Claim Rejections – 35 USC § 112

Claims 1-5 and 8 stand rejected under 35 U.S.C. 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5 and 8 stand rejected because the recitation of “heterocyclyl” throughout the claims is allegedly indefinite.

Applicants respectfully disagree and traverse the rejection.

Applicants respectfully submit that a 4- to 10-membered heterocyclyl is defined in Applicants’ specification as a “mono- or polycyclic, heterocyclic radical having 4 to 10 ring atoms and up to 3 heteroatoms or hetero groups from the series N, O, S, SO, SO₂” (see

Application No.: 10/524,956
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page 7, lines 14-16). It is in a preferred embodiment that the ring has 1 heteroatom or hetero group.

Accordingly, Applicants respectfully submit that “heterocyclyl” is clearly defined in Applicants’ specification, and respectfully request the withdrawal of the rejection.

Claims 1-5 have been amended to recite the variable R4 in the alternative. Withdrawal of the rejection is respectfully requested.

Claim 8 has been amended to recite a “pharmaceutical composition”. Withdrawal of the rejection is respectfully requested.

Claims 1-5 and 8 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for other forms, allegedly does not reasonably provide enablement for solvates.

The Examiner alleges that the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope that these claims. The Examiner also alleges that “the numerous examples presented all failed to produce a solvate and that these cannot be simply willed into existence”.

Applicants respectfully disagree and traverse the rejection.

An application disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken in compliance with the enabling requirement of the first paragraph 35 U.S.C. §112, unless there is reason to doubt the objective truth of statements contained therein relied on for enabling support. *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). *Fiers v. Revel*, 984 F.2d 1164, 24 USPQ2d 1601 (Fed. Cir. 1993). The inventors in the instant disclosure have described how to make and use the invention in terms which correspond in scope to those in the claims. Applicants respectfully submit the Office action fails to

Application No.: 10/524,956
Response dated September 29, 2008
Reply to Office action of April 2, 2008

provide sufficient evidence or objective reasoning to raise doubt about the truth or accuracy of the inventors' statements on this point. The burden of proof rests on the Patent and Trademark Office to show non-enablement and the evidence of record, as discussed above, fails to meet the burden of proof.

Applicants respectfully submit that Applicants' specification provides sufficient enablement for the claimed invention, and respectfully request reconsideration and withdrawal of the rejection.

Claim Rejections - 35 USC § 103

Claims 1-5 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Miyashita et al (Heterocycles, 1990, 31(7), 1309-14).

The Examiner alleges that the difference between the reference and the instant Application is the substitution at the R⁴ variable, methyl versus Applicants's pentan-3-yl. The Examiner further alleges that since a methyl group is considered a homolog of hydrogen these compounds are considered equivalent. The Examiner also refers to MPEP 2144.09 which states "Compounds which are ... homologs (compounds differing regularly by the successive addition of the same chemical group, e.g. by -CH₂- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. *In re Wilder*, 563 F.2d 457, 195 USPQ 426 (CCPA 1977).

Applicants respectfully disagree and traverse the rejection.

The Examiner refers to methyl and hydrogen groups as being considered homologs. However, Applicants respectfully submit that the claimed invention recites pentan-3-yl, not hydrogen, and respectfully request clarification of the Examiner's statement.

The Examiner refers to MPEP 2144.09 and *In re Wilder* in the rejection. However, Applicants respectfully submit that the same section of MPEP also states that "Isomers having the same empirical formula but different structures are not necessarily considered equivalent by chemists skilled in the art and therefore are not necessarily suggestive of each other. *Ex parte Mowry*, 91 USPQ 219 (Bd. App. 1950) (claimed cyclohexylstyrene

Application No.: 10/524,956
Response dated September 29, 2008
Reply to Office action of April 2, 2008

not *prima facie* obvious over prior art isohexylstyrene). Similarly, homologs which are far removed from adjacent homologs may not be expected to have similar properties. *In re Mills*, 281 F.2d 218, 126 USPQ 513 (CCPA 1960) (prior art disclosure of C8 to C 12 alkyl sulfates was not sufficient to render *prima facie* obvious claimed C1 alkyl sulfate)."

MPEP 2144.09 also states that "Homology and isomerism involve close structural similarity which must be considered with all other relevant facts in determining the issue of obviousness. *In re Mills*, 281 F.2d 218, 126 USPQ 513 (CCPA 1960); *In re Wiechert*, 370 F.2d 927, 152 USPQ 247 (CCPA 1967). Homology should not be automatically equated with *prima facie* obviousness because the claimed invention and the prior art must each be viewed "as a whole." *In re Langer*, 465 F.2d 896, 175 USPQ 169 (CCPA 1972) (Claims to a polymerization process using a sterically hindered amine were held unobvious over a similar prior art process because the prior art disclosed a large number of unhindered amines and only one sterically hindered amine (which differed from a claimed amine by 3 carbon atoms), and therefore the reference as a whole did not apprise the ordinary artisan of the significance of hindered amines as a class.)."

Applicants respectfully submit that the Examiner has not provided any evidence supporting the Examiner's arguments and that a *prima facie* case of obviousness has therefore not been established. On the contrary, Applicants respectfully submit that there is no guidance in Miyashita to modify any of the compounds of Miyashita to arrive at the claimed invention.

Accordingly, Applicants respectfully submit that the claimed invention is non-obvious over Miyashita, and respectfully request that the rejection be withdrawn.

Claims 1-5 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Schmidt et al (CH 396924).

The Examiner alleges that the difference between the reference and the instant Application is the substitution at the R⁴ variable, isopropyl versus Applicants's pentan-3-yl. The Examiner also alleges that the same homolog used above applies here too.

Applicants respectfully disagree and traverse the rejection.

Application No.: 10/524,956
Response dated September 29, 2008
Reply to Office action of April 2, 2008

Applicants reiterate the arguments made in response to the rejection over Miyashita above, and refer to MPEP 2144.09 as mentioned above. Applicants therefore respectfully submit that the Examiner has not established a *prima facie* case of obviousness. On the contrary, Applicants respectfully submit that there is no guidance in Schmidt to modify any of the compounds of Schmidt to arrive at the claimed invention.

Accordingly, Applicants respectfully submit that the claimed invention is non-obvious over Schmidt, and respectfully request that the rejection be withdrawn.

Other references

The Examiner also cites additional references in the Office Action mailed on April 2, 2008 (CH 396923, CH 396927, GB 973361 and DE 1156415), and alleges that these references have similar substituents at R⁴ as those mentioned above.

Applicants respectfully invite the Examiner to point out sections or compounds in these references which may be relevant in the context of the claimed invention. Alternatively, if the arguments presented above in response to the rejections over Miyashita and Schmidt are deemed pertinent to the facts in CH 396923, CH 396927, GB 973361 and/or DE 1156415, Applicants respectfully invite the Examiner to indicate that the claimed invention is also non-obvious over these references.

Double Patenting

Applicants note that no obviousness-type double patenting rejections were made over co-pending applications 10/525,115; 10/525,119; 10/556,437 and 10/556,224. Obviousness-type double patenting rejections over these co-pending applications were considered but not applied.

Application No.: 10/524,956
Response dated September 29, 2008
Reply to Office action of April 2, 2008

In view of the above, Applicants respectfully submit that all objections and rejections have been addressed and that the application is now in condition for allowance. If the Examiner feels that a telephone interview would be helpful in advancing prosecution of this application, the Examiner is invited to contact the undersigned at the number below.

Respectfully submitted,

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